VIRGINIA INHALATION TOXICOLOGY ADVISORY GROUP

MINUTES

FIRST MEETING
JANUARY 15, 2009

TIME AND PLACE: 9:00AM – 3:45PM
DEQ Central Office
629 E. Main Street
Richmond, VA 22469
Conference Room A

PRESIDING: Patricia McMurray, DEQ Risk Assessor Program Manager

MEMBERS PRESENT:

Chris Bednar, Smurfit-Stone, (VMA)
Robert Corley, Ph. D., Virginia State University
Jim Gould, Sierra Club
John Morris, Ph.D., University of Connecticut (SOT)
Debbie Mulrooney, Dupont (VMA)
Kevin Wallace, M. D., University of Virginia
Kimber White, Ph. D., Virginia Commonwealth University

STAFF PRESENT:

Alan Anthony, Risk Assessor, Air Toxics (Timekeeper)
Ahmet Bulbulkaya, Risk Assessor, Office of Remediation Programs
Patty Buonviri, Air Toxics
Mike Dowd, Air Director, Office of Air Quality Programs
James Golden, Deputy Director for Program Development, Office of Executive Management/ Public Constituent Affairs
Kyle Newman, Risk Assessor, Office of Remediation Programs (Recorder)
Durwood Willis, Director, Office of Remediation Programs

The meeting began by outlining the purpose of the advisory group. VADEQ's air toxics regulations were last examined many, many, years ago. DEQ expressed hope that the meetings will bring together a wide variety of interests while providing valuable technical expertise and transparency. Emphasis was placed on this meeting being the start of the process, and with DEQ starting to acquire enhanced monitoring more will hopefully be done in the future.

Participants introduced themselves and stated their backgrounds in inhalation toxicology. The acronym of VINTAG- Virginia Inhalation Toxicology Advisory Group, was proposed and accepted without disagreement.

The ground rules of the meetings were outlined, which are the same as all public meetings as stated in the DEQ guidelines even though this meeting did not technically require them since the creation of the group was not required by law. During the proceedings the public may attend but only VINTAG members may participate. Members of the public may ask questions or comment at the discretion of the group. DEQ staff may ask questions but are not allowed to express opinions on the subject matter. Minutes will be taken and the proceedings will be recorded. A draft of the minutes will be circulated within 10 days of the meeting and a final version will be published after all VINTAG members have approved. DEQ will summarize the group's deliberations and recommendations in a final report, and if consensus is not reached the differences will be outlined in the report. It was suggested that members submit comments on the minutes directly to DEQ via email rather than circulate comments on the minutes to the entire group. All members agreed to the ground rules and proposed approach for reviewing and approving of minutes.

DEQ staff gave a Power Point Presentation "Significant Ambient Air Concentration(s): Is there a Technical Basis for Revaluation?" The presentation highlighted historical approach to non-cancer air regulation and will be available online.

It was noted that in the Waste Division there is a well defined hierarchy of sources for screening values etc. that includes IRIS, PPRTV, CalEPA, and other sources. Air regulations do not have a similar hierarchy. DEQ would like a good foundation and methodology to evaluate air concentrations, but is not looking for VINTAG to develop specific numbers. New assessments and guidance documents are constantly being produced, so some flexibility should be built into the final recommendations.

Six meetings are planned, one every month through June with a final report being released in August. Participants should be flexible as the process may be longer or shorter than intended. Travel needs are understood, and members may participate via conference call if needed. However, Virginia regulations require that the location the member is calling from be made known and available to the public.

The definition of RfC was discussed, and it was noted that the definition will in part determine the approach. DEQ Staff expressed optimism that the definition would be modified slightly to reflect the current science. Later presentations will discuss sensitive subpopulations. Emphasis was placed again on the fact that VINTAG is not to develop numbers for the regulations, but rather a methodology that could be used by DEQ staff and the public to produce reproducible values. The final report in August may not detail the exact methodology but instead will focus more on the toxicological aspects of the methodology.

DEQ staff outlined plans for the website which is not online at the moment. The reference list will include all HAP compounds. Data from EPA and CalEPA (including older guidance) will be highlighted because they provide extensive background information. If ATSDR values are used those documents will be posted as well. ERPGs and AEGLs will be posted for members but they cannot be distributed outside the group due to copyright laws. Guidance from Europe (OECD) will not be included because of significant disagreement between the EU and US regarding methodologies and approaches. EPA Air Toxics/Research Triangle data will be on the site as well as PPRTVs. The recent NAS review on risk assessment will also be posted, and some of its recommendations may influence those made by VINTAG. While the website is not up at the moment, DEQ can make and send out DVDs containing all of the references.

ADJORN FOR BREAK

DEQ Staff gave a presentation titled "Comparison of Methods for Deriving Non-Cancer Toxicity Factors" which reviewed the accepted toxicological approaches used by EPA and CalEPA. Definitions of NOAEL/LOAEL vs. Critical Effect were discussed, as well as organ-specific NOAELs. The fact that the definition of "adverse" can differ depending on approach was noted. The presentation spawned a discussion about BMC model approaches, and an evaluation of BMC models was added to the list of Action Items based on potential issues that may arise if the BMC approach is recommended.

When approaches to calculating POD were discussed, a question was asked if different equations may be used for different endpoints by DEQ. The possibility is left open, but a note of caution was struck because while these approaches are based on empirical approaches, relevant definitions are mechanistic. When developmental toxicity was discussed, the fact that some of the total dose from some airborne exposures consists of both an oral and an inhalation component was raised by some members. While this may not affect systemic endpoints, it makes predicting respiratory injury more difficult. Other members noted that the concept of a DAF is controversial, and its use will be significantly modified based on a 2002 review with a greater emphasis on PBPK modeling. The applicability of PBPK modeling to different breathing types was affirmed.

Other issues raised during the presentation were the definitions of toxicodynamics vs. toxicokinetics, how uncertainty factors are applied to infants and how studies examine these questions in an ethical manner. One member noted that most sub-chronic studies performed on test species begin at the sub-adult life stage, and thus may not capture many developmental effects. A brief discussion ensued about the appropriateness of some test species. Rats and mice were said to have been used more based on the greater amounts of data for those species, though it was mentioned that avian species are better models for cardiovascular disease and exposure to organophosphates. While MFs have been discontinued, one member noted their utility for compounds where some approaches would be nonsensically conservative, such as gum arabic, table salt, and oxygen. An MF could also be used when an endpoint exists in a test species but not humans due to physiological differences. Members noted that the selection of uncertainty factors could have a similar effect, and that while some effects occur in test species but not humans,

often these are indicative of other effects. The differences in cancer location between rats (nasal breathers) and humans (mouth and nasal breathers) were cited as an example.

DEQ reaffirmed that VINTAG will be making recommendations on procedure with the goal of having an individual not familiar with toxicology being able to produce a numeric screening value. One member asked about the potential for VADOH to provide technical assistance, but currently DOH has only one toxicologist and budget constraints will limit their ability to provide assistance in the future. Another member mentioned that European REACH guidance could provide valuable information. Adding REACH data was added to the list of Action Items, focusing on HAPs.

Members raised the question on how to address pragmatic standards, for example when a proposed RfC may be lower than the detection limit. DEQ Staff noted that those concerns would be addressed internally within the agency, and expressed that they would like to see a table that could be usable by permit writers with descriptions of how those numbers were derived. The emphasis should be on developing the numbers, then DEQ will determine how best to use them. However, if numbers are put into the regulations they are not flexible. DEQ expressed a desire that some flexibility could be built into the regulations to allow for future updates.

Next scheduling for the next meeting was then discussed, as well as rules regarding continued participation. It was suggested that if a member missed three meetings they would be removed from the group. DEQ noted that there are no procedures for removing someone from the advisory group, and that any removals would have to evaluate participation between meetings and not just attendance. The end of February was proposed as a possible timeframe. Thursdays were also proposed as a regular meeting day. The group reached consensus on the date of February 19 at the same time and place, with a possible delay of the start time to 9:30. One member asked if they needed to be in a public place if they were to call in, but regulations state that if a member of the public wants to participate on the call they must be able to have access- private offices are fine. DEQ has limited teleconferencing abilities, but DEQ will investigate whether the internet service Skype could be used. Technical support will be provided in an email to be sent out at a later date.

BREAK FOR LUNCH

DEQ staff gave a presentation titled “Chemical Specific Comparison of Non-Cancer Toxicity Factors.” The presentation compared a list of RfC and REL values from EPA and CalEPA respectively, detailing how each value was derived. Issues about quality control in the process were raised, but members familiar with the process stated that peer review plays a significant role, adding another layer of scrutiny to supporting studies on top of journal submission driven peer review. Agency staff at EPA and CalEPA are also highly selective in the studies that they use to develop values, adding another layer of quality control. Conservatism is built into the process by usually selecting the most conservative NOAEL if several organ systems are evaluated.

One member noted that the final RfC/REL values are not particularly precise, and are primarily driven by uncertainty factors. Another raised the issue of uncertainty as a function of exposure- that there is as much uncertainty in dispersion and emission models as toxicological ones. The economic impact of even small differences between values was raised by some members. The possibility of using a range of numbers was suggested, but the discussion of specific numbers was deferred to another time since the group's task is process driven. One member noted that things such as economic considerations should be included in discussions for the sake of transparency.

A member asked why some compounds had more than one listed reference. Other members stated that often different components of the same study are published as separate manuscripts. Agencies will look at a range of different studies and select the one with the most sensitive endpoint and of appropriate quality. Noted that agencies prefer to use BMCs over NOAELs, though in some instances a value like an MRL from ATSDR may be accepted without adding uncertainty factors, and that in most instances a high quality rat study will have preference over a poorly conducted human study.

The use of the DAF was noted to be problematic in regards to the location of an effect. Members stated that scientific grounding was difficult for some compounds because of widely ranging scientific views and interpretations. Several members believed that the question of what constitutes an "adverse" effect plays a significant role in the selection of values, since some critical effects listed are temporary. However, members agreed that scientifically many of the differences between the values resulting from each approach were generally not statistically significant. DEQ offered to present the relative differences between the two sets of values before the next meeting.

One member asked why some studies like those for arsenic did not expose test animals through the inhalation route. Other members responded by noting that for systemic effects the route of exposure is not as important as overall dose. For oral studies, researchers can assume the value of the absorbed dose and compare that to a conservative assumption that 100% of the compound is absorbed through the lungs.

Once the presentation ended a member asked for clarification as to what VINTAG's task was in relation to non-cancer compounds. DEQ requested that the group come up with a process for developing DEQ toxicity numbers or a recommendation on a set of numbers (i.e. EPA or CalEPA) to use. Many values from both agencies were developed 20 years ago. DEQ staff feels that there are many options, including a hybrid approach that may utilize data from both. Members asked if DEQ would prefer to perform calculations or just select a value. DEQ stated a preference for picking a value because of limited resources, but is open to other considerations. However, the agency does not have the resources to start from scratch. The approach in the Waste Division is to use a hierarchy of preferred values.

The air toxics programs of other states were discussed. California, New Jersey, and Texas programs were specifically mentioned.

One member asked what the potential consequences of the group's recommendations would be and potential legal action if a citizen claims that standards selected by DEQ are not protective enough. Members noted that the goal of the group is to come down on the side of sound science. One noted that simply taking the most conservative value could make it seem that exposure to a compound was worse than what it actually is.

Members inquired about exactly which compounds DEQ was responsible for regulating. DEQ staff stated that under federal law DEQ is not required to regulate any, but DEQ has chosen to focus on the HAPs. With the need to examine more than 200 different compounds, members noted the need for some sort of review cycle, perhaps every 4 years. The possibility of only using values based on BMC was discussed, but was deemed impractical because of a lack of data for many compounds. The lack of resources at DEQ was deemed to be an additional factor in the review process, and selecting one number from either CalEPA or EPA was suggested as the most practical option. Members noted that for some compounds the difference between the two sets of numbers was quite large, as much as 100 fold. The group decided that VINTAG needed to develop some sort of review process to evaluate the CalEPA and EPA datasets to determine if either was more accurate.

One member suggested that a table be set up comparing VA SAACs to the CalEPA and EPA numbers. DEQ staff emphasized that the SAACs are not health based numbers, and that it should be relatively straightforward to determine if the CalEPA or EPA approach is better. A member suggested that both datasets could be compared to another, such as the NJ air toxics values. Support was expressed for an approach that would assume that values within an order of magnitude were essentially the same. One member suggested that when the differences were that small, the more conservative could be picked. When values were greater than an order of magnitude, it could be assumed that there is a scientific dispute over the toxicity of the compound, and that dispute could be resolved by DOH review.

Members asked if VINTAG would be responsible for developing the thought process involved in these reviews. DEQ replied in the affirmative, with a preference towards a decision tree style framework. The first step of that process would have to be establishing what constitutes a significant difference between the CalEPA and EPA values. One member suggested that if there was only one number to take it, and if the difference between numbers was less than 3 fold to take the most recent. If the difference were greater than that then it would require a more valuative process. One member expressed a preference for the BMD approach. A brief break was taken and members were urged to consider what sort of in-depth criteria should be used during the review process.

After the break the group worked to develop a tentative flow chart for the review process, the final product included in these minutes as Attachment 1. The need to determine the source of differences between the CalEPA and EPA numbers was determined to be a key requirement in the process. Members suggested that DEQ produce a table with detailed information about each study that included the relative difference between the values. DEQ agreed to create and distribute a table with that information to group members. For

compounds with significant differences, it was noted that DEQ could evaluate relevant studies and reference values for a limited number of compounds. A brief review of the CalEPA and EPA datasets indicated that only about 33 compounds had different values, and the vast majority of them differed by less than 10 fold. DEQ staff noted that as the regulations stand, there is very limited flexibility for air toxics in comparison to Brownfields and other programs due to public comment periods etc. After some discussion, members agreed on a screening value for the review process of a 3-fold difference between the datasets.

After the figure was developed, the group revisited the Action Items. Members agreed to defer discussion of BMC models until the next session. DEQ agreed to review and distribute the REACH guidelines in addition to the NAS risk assessment review before the next meeting. Members with access to the Texas ESL air toxics values agreed to distribute them to the rest of the group, even though they were determined not be firm regulatory screening values.

Members then critiqued the meeting. Reactions were generally positive. Members found the meeting informative, and felt as if a reasonable path forward had been identified. Some individuals had come into the meeting feeling overwhelmed, but were pleased that a process had started to be developed. Many expressed surprised at the speed and cohesiveness with which the group was able to address its tasks. Members felt that the meeting was well structured, but expressed hope that the next meeting would see an increase in participation from some members.

DEQ expressed optimism that non-cancer issues could be resolved and discussions on carcinogens could begin during the next meeting. DEQ agreed to send out contact information for all members of the group, as well as a copy of the minutes for approval within 10 days. Members agreed that DEQ staff should be the point of contact for all discussions involving minutes, and that members would not be referred to by name in the minutes unless specifically requested. The group agreed to make the attire for all future meetings business casual, and the meeting was adjourned approximately an hour early.

ATTACHMENT 1: Tentative Decision Tree to Determine Chronic Inhalation Reference Values